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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,538	10/12/2001	Michael P. McLeod	7504-80241	1515
24628	7590	09/26/2006	EXAMINER	
WELSH & KATZ, LTD 120 S RIVERSIDE PLAZA 22ND FLOOR CHICAGO, IL 60606			OROEZA, FRANCES P	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/976,538

Applicant(s)

MCLEOD ET AL.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 7/13/06 (Amendment).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Amendment***

1. The Applicant amended independent claim 1 in the reply filed 7/13/06, hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

### ***Claim Rejections - 35 USC § 103***

2. Claims 1, 2 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platt (US 6730025) in view of Kuo et al. (US 5782773) and Stetzler et al. (US 6754355) and Brown (US 5899855).

Platt discloses a physiological signal acquisition device comprising a hand-held portable processing element (2) with cartridge (4), and an acquisition unit (1) with sensors (6) (figure 1; col. 1 @ 4-8; col. 4 @ 13-34). The concept of disposing the acquisition unit on the chest amounts to an intended use limitation of which Platt performs or is inherently capable of performing. The processing element (2) is controlled by a CPU / a microprocessor which executes the software stored in the cartridge (col. 3 @ 4-9; col. 5 @ 65-67). The acquisition unit (1) comprises a digital signal processor (col. 4 @ 45-50) adapted to filter the electrocardiogram signal. The filtering occurs in the amplifier (10), the amplifier comprising a high pass filter and a low pass anti-aliasing filter (col. 5 @ 37-40). The digital signal process, including the analogue to digital converter controlled by signals (-CS and CLK), is controlled by processing element control system, the CPU / microprocessor. The cartridge (4) in the processing element (2) contains an application specific program to control the display and user interface (col. 4 @ 30-34; col. 4 @ 30-34 and 50-55; col. 5 @ 65-67).

As discussed in the previous paragraph of this action, Platt discloses the claimed invention except for the generation of a twelve lead electrocardiograph and the acquisition element being a digital signal processor with a plurality of filters.

Kuo et al. teach cardiac monitoring by generating a 3-D representation of cardiac signals using a twelve lead electrocardiograph, the signals being processed by a digital signal processor comprising a plurality of filters for the purpose gather cardiac signals that are signals are filtered to remove noise and undesired components so heart disease can be diagnosed. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a twelve lead electrocardiograph, the signals being processed by a digital signal processor comprising a plurality of filters in the Platt system in order to use the most widely used EKG recording technology in clinical application so the physician can evaluate signals of optimal quality enabling the physician to inspect the recorded cardiac waveform for abnormal features and accurately provide diagnosis of heart disease (abstract; col. 1 @ 6-10, 32-34; col. 2 @ 42-54; col. 5 @ 26-39).

As discussed in the previous three paragraphs of this action, modified Platt discloses the claimed invention except for the plurality of filters being programmable.

Stetzler et al. teach signal processing using a digital signal processor with programmable filters for the purpose of customizing the range of the filters used to process physiological signals. It would have been obvious to one having ordinary skill in the art at the time of the invention to provide programmable filters in the modified Platt system in order to process the cardiac signals with filters programmed to the desired range for the application, providing high

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quality signals that can be used by the physician to diagnosis the condition of the patient, hence avoiding delays in providing appropriate treatment (col. 2 @ 51-61; col. 3 @ 14-27; col. 4 @ 3-11).

As discussed in the previous five paragraphs of this action, modified Platt discloses the claimed invention except the application specific program of the cartridge that controls the display and user interface being a windows- based operating system.

Brown teaches Nintendo <sup>TM</sup> GAME BOY <sup>TM</sup> system applications using a windows-based operating system with menus, submenus and icons for the purpose of controlling the hand-held computer device. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a windows- based operating system in the modified Platt system in order to provide the system operator with a means to easily select the desired event or operating parameters (figure 1; col. 4 @ 54-61; col. 5 @ 30-33; col. 14 @ 12- 67; col. 17 @ 26-28, 44-50; col. 18 @ 37-52, 57-64; col. 19 @ 6-8, 44-55; col. 23 @ 42-65).

3. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platt (US 6730025) in view of Kuo et al. (US 5782773) and Stetzler et al. (US 6754355) and Brown (US 5899855) and further in view of Rohde (US 5876351). As discussed in paragraph 2 of this action, modified Platt discloses the claimed invention except for the display being an LCD with sufficient resolution to display waveforms.

Rohde teaches data display on a GAMEBOY <sup>TM</sup> system using an LCD (20) with sufficient resolution to display waveforms for the purpose monitoring the ECG of the patient.

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It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an LCD with sufficient resolution to display waveforms in the modified Platt system in order to provide a proven GAMEBOY™ communication means for signal display (col. 5 @ 18-21).

4. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Platt (US 6730025) in view of Kuo et al. (US 5782773) and Stetzler et al. (US 6754355) and Brown (US 5899855) and further in view of Skelton et al. (US 6292692). As discussed in paragraph 2 of this action, modified Platt discloses the claimed invention except for the screen being a touch screen interface.

Skelton et al. teach communications interface using a touch screen for the purpose of making input selection known to a controller/ microprocessor. Absent any teachings of criticality of unexpected results, merely changing the input means from a joypad and control buttons to a touch screen interface would be an obvious design choice.

5. Claims 6-11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platt (US 6730025) in view of Kuo et al. (US 5782773) and Stetzler et al. and Brown (US 5899855) further in view of Rockwell et al. (US 6141584). As discussed in paragraph 2 of this action, modified Platt discloses the claimed invention except for: a read only memory card (claims 6 and 7), wireless communication using an infrared transceiver (claim 8) or a radio frequency transceiver (claim 9), an audio recording unit (claim 10), signal conditioning circuits (claim 11) and signal analysis and interpretation (claim 14).

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As to a memory card, Rockwell et al. teach data storage using a read only memory card for the purpose of recording the ECG and audio data in memory. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the read only memory card in the modified Platt system in order to provide a mechanism enabling the collected data to be reviewed and analyzed at a future time (col. 11 @ 3-16).

As to wireless communication, Rockwell et al. teach wireless communication using infrared and radio frequency communication signals for the purpose of conveying information to remote locations. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used infrared and radio frequency signals in the modified Platt system in order to enable sharing of information and report generation to optimize the patient's treatment (col. 5 @ 2-17).

As to an audio unit, Rockwell et al. teach event recording using an audio unit for the purpose of documenting the events associated with patient care. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an audio unit in the modified Platt system in order to provide a comprehensive understanding of the condition of and the treatment afforded the patient so the events are accurately reconstructed (col. 10 @ 1-9).

As to signal analysis, Rockwell et al. teach cardiac signal evaluation using signal analysis for the purpose of detecting the cardiac rhythm of the heart. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used signal analysis in the modified Platt system in order to alert the user to cardiac condition, so conditions such as ventricular tachycardia requiring immediate medical attention can be identified and treated (col. 10 @ 49-51).

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6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Platt (US 6730025) in view of Kuo et al. (US 5782773) and Stetzler et al. (US 6754355) and Brown (US 5899855) and further in view of Mogi (US 5873838). As discussed in paragraph 2 of this action, modified Platt discloses the claimed invention except for a baseline sway filter.

Mogi teaches electrocardiogram signal processing using a notch filter for the purpose of removing the sway / fluctuation produced by noise from the electrocardiogram signal. It would have been obvious to one having ordinary skill in the art at the time of the invention to have a notch filter for removing sway from the baseline electrocardiogram signal in the modified Platt system in order to provide a mechanism to produce an accurate and appropriate electrocardiogram waves for the processing unit so optimal diagnosis and treatment can be provided (abstract; col. 6 @ 34-44).

7. Claims 1, 2 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platt (US 6730025) in view of Flach et al. (US 6773396) and Kuo et al. (US 5782773) and Stetzler et al. (US 6754355) and Brown (US 5899855).

Platt discloses a physiological signal acquisition device comprising a hand-held portable processing element (2) with cartridge (4), and an acquisition unit (1) with sensors (6) (figure 1; col. 1 @ 4-8; col. 4 @ 13-34). The concept of disposing the acquisition unit on the chest amounts to an intended use limitation of which Platt performs or is inherently capable of performing. The processing element (2) is controlled by a CPU / a microprocessor which executes the software stored in the cartridge (col. 3 @ 4-9; col. 5 @ 65-67). The acquisition unit (1) comprises a digital signal processor (col. 4 @ 45-50) adapted to filter the electrocardiogram



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signal. The filtering occurs in the amplifier (10), the amplifier comprising a high pass filter and a low pass anti-aliasing filter (col. 5 @ 37-40). The digital signal process, including the analogue to digital converter controlled by signals (-CS and CLK), is controlled by processing element control system, the CPU / microprocessor. The cartridge (4) in the processing element (2) contains an application specific program to control the display and user interface (col. 4 @ 30-34; col. 4 @ 30-34 and 50-55; col. 5 @ 65-67).

As discussed in the previous paragraph of this action, Platt discloses a device that is capable of being disposed on the chest of the patient and Flach et al. support this teaching.

Flach et al. teach signal acquisition using a data collection unit (102A) disposed on the chest of the patient that is connected to relatively short lead wires for the purpose of monitoring the ECG of the patient (figure 2; col. 7 @ 21-24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used the data collection / data acquisition unit disposed on the chest of the patient that is connected to relatively short leadwires in the Platt system in order to provide a proven convenient compact system that secures the monitor to the patient enabling continuous data collection for the ambulatory patient (col. 1 @ 44-51).

As discussed in the previous three paragraphs of this action, modified Platt discloses the claimed invention except for the generation of a twelve lead electrocardiograph and the acquisition element being a digital signal processor with a plurality of filters.

Kuo et al. teach cardiac monitoring by generating a 3-D representation of cardiac signals using a twelve lead electrocardiograph, the signals being processed by a digital signal processor comprising a plurality of filters for the purpose gathering cardiac signals that are optimally

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filtered to remove noise and undesired components so heart disease can be diagnosed. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a twelve lead electrocardiograph, the signals being processed by a digital signal processor comprising a plurality of filters in the modified Platt system in order to use the most widely used EKG recording technology in clinical application so the physician can evaluate signals of optimal quality, enabling the physician to inspect the recorded cardiac waveform for abnormal features and accurately provide diagnosis of heart disease (abstract; col. 1 @ 6-10, 32-34; col. 2 @ 42-54; col. 5 @ 26-39).

As discussed in the previous five paragraphs of this action, modified Platt discloses the claimed invention except for the plurality of filters being programmable.

Stetzler et al. teach signal processing using a digital signal processor with programmable filters for the purpose of customizing the range of the filters used to process physiological signals. It would have been obvious to one having ordinary skill in the art at the time of the invention to provide programmable filters in the modified Platt system in order to process the cardiac signals with filters programmed to the desired range for the application, providing high quality signals that can be used by the physician to diagnosis the condition of the patient, hence avoiding delays in providing appropriate treatment (col. 2 @ 51-61; col. 3 @ 14-27; col. 4 @ 3-11).

As discussed in the previous seven paragraphs of this action, modified Platt discloses the claimed invention except the application specific program of the cartridge that controls the display and user interface being a windows- based operating system.

Brown teaches Nintendo™ GAME BOY™ system applications using a windows-based operating system with menus, submenus and icons for the purpose of controlling the hand-held computer device. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a windows-based operating system in the modified Platt system in order to provide the system operator with a means to easily select the desired event or operating parameters (figure 1; col. 4 @ 54-61; col. 5 @ 30-33; col. 14 @ 12- 67; col. 17 @ 26-28, 44-50; col. 18 @ 37-52, 57-64; col. 19 @ 6-8, 44-55; col. 23 @ 42-65).

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Rohde teaches data display on a GAMEBOY™ system using an LCD (20) with sufficient resolution to display waveforms for the purpose monitoring the ECG of the patient. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an LCD with sufficient resolution to display waveforms in the modified Platt system in order to provide a proven GAMEBOY™ communication means for signal display (col. 5 @ 18-21).

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Brown (US 5899855) and further in view of Skelton et al. (US 6292692). As discussed in paragraph 7 of this action, modified Platt discloses the claimed invention except for the screen being a touch screen interface.

Skelton et al. teach communications interface using a touch screen for the purpose of making input selection known to a controller/ microprocessor. Absent any teachings of criticality of unexpected results, merely changing the input means from a joypad and control buttons to a touch screen interface would be an obvious design choice.

10. Claims 6-11 and 14 are rejected under 35 U.S.C. 103(a) as obvious over Platt (US 6730025) in view of Flach et al. (US 6773396) and Kuo et al. (US 5782773) and Stetzler et al. (US 6754355) and Brown (US 5899855) and further in view of Rockwell et al. (US 6141584). As discussed in paragraph 7 of this action, modified Platt discloses the claimed invention except for: a read only memory card (claims 6 and 7), wireless communication using an infrared transceiver (claim 8) or a radio frequency transceiver (claim 9), an audio recording unit (claim 10), signal conditioning circuits (claim 11) and signal analysis and interpretation (claim 14).

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remote locations. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used infrared and radio frequency signals in the modified Platt system in order to enable sharing of information and report generation to optimize the patient's treatment (col. 5 @ 2-17).

As to an audio unit, Rockwell et al. teach event recording using an audio unit for the purpose of documenting events associated with patient interaction and care. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an audio unit in the modified Platt system in order to provide a more comprehensive understanding of the patient's condition and the treatment afforded the patient so the events are accurately reconstructed (col. 10 @ 1-9).

As to signal analysis, Rockwell et al. teach cardiac signal evaluation using signal analysis for the purpose of detecting the cardiac rhythm of the heart. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used signal analysis in the modified Platt system in order to alert the user to cardiac condition, so conditions such as ventricular tachycardia requiring immediate medical attention can be identified and treated (col. 10 @ 49-51).

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Platt (US 6730025) in view of Flach et al. (US 6773396) and of Kuo et al. (US 5782773) and Stetzler et al. (US 6754355) and Brown (US 5899855) and further in view of Mogi (US 5873838). As discussed in paragraph 7 of this action, modified Platt discloses the claimed invention except for a baseline sway filter.

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Mogi teaches electrocardiogram signal processing using a notch filter for the purpose of removing the sway / fluctuation produced by noise from the electrocardiogram signal. It would have been obvious to one having ordinary skill in the art at the time of the invention to have a notch filter for removing sway from the baseline electrocardiogram signal in the modified Platt system in order to provide a mechanism to produce an accurate and appropriate electrocardiogram waves for the processing unit so optimal diagnosis and treatment can be provided (abstract; col. 6 @ 34-44).

#### *Other Prior Art Cited*

12. The prior art made of record and not relied upon is considered pertinent to the Applicant's disclosure. US 6654631 to Sahai teaches the use of a twelve lead EKG with a portable monitoring device (col. 1 @ 64).

#### *Statutory Basis*

13. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### *Conclusion*


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3766

*FPO*  
*9/19/06*

  
Robert E. Pezzuto  
Supervisory Patent Examiner  
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